

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE INCYTE SHAREHOLDER	:	CIVIL ACTION
LITIGATION	:	
	:	No. 13-365

MEMORANDUM

Juan R. Sánchez, J.

February 21, 2014

Plaintiff City of Lakeland Employees' Pension Plan brings this consolidated securities fraud class action on behalf of all persons who purchased the common stock of Incyte Corporation (Incyte or the Company) between April 26, 2012, and August 1, 2012 (the Class Period). Plaintiff asserts claims against Incyte and three of its officers—Chief Executive Officer Paul A. Friedman, Chief Commercial Officer Patricia S. Andrews, and Executive Vice President and Chief Drug Development and Medical Officer Richard S. Levy—for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 issued by the Securities and Exchange Commission (SEC).

Defendants have filed a motion to dismiss the Complaint for failure to state a claim pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) and the Private Securities Litigation Reform Act of 1995 (PSLRA). For the reasons discussed below, the Court will grant Defendants' motion to dismiss and dismiss Plaintiff's claims without prejudice. Plaintiff shall have thirty days from the date of the Order accompanying this Memorandum to amend its Complaint consistent with this Memorandum.

FACTS

Incyte is a biopharmaceutical company founded in 1991 that develops and commercializes small molecule drugs for treatment of various diseases. Its first and only

commercially available product is a drug called Jakafi. First synthesized in 2005, Jakafi is intended to improve symptoms of patients with myelofibrosis, a severe, life-threatening bone marrow disease. In connection with obtaining FDA approval of Jakafi, Incyte conducted several clinical trials, whose subjects demonstrated significant improvements in certain symptoms after taking the drug. The clinical trials also documented patient discontinuation rates (or dropout rates)—the rate at which patients stop using Jakafi for whatever reason. The discontinuation rates recorded during the clinical trials were approximately 14% at the 24-week mark and 18% at the 48-week mark. These trials excluded severely ill patients with a platelet count below 100,000 and a projected life-span of six months or less.

The FDA approved Jakafi for the treatment of intermediate or high-risk myelofibrosis on November 16, 2011, making it the first myelofibrosis drug to obtain such approval. Immediately following FDA approval Incyte launched Jakafi for sale and the first patient received it commercially on November 23, 2011. Plaintiff alleges after the FDA approved Jakafi and during the Class Period, Incyte experienced heightened discontinuation of Jakafi among its core patient group, which consisted of severely ill patients, many of whom had not participated in clinical studies. Severely ill patients were considered the core patient group for Jakafi because physicians tended to prescribe the drug only when a patient reached advanced stages of myelofibrosis. According to a confidential source (a former employee), there was no basis to project substantial sales from any patients with less than severe symptoms. This is because myelofibrosis is generally considered an indolent disease, which develops slowly and incrementally over time. Doctors therefore evaluate the symptoms taking a “wait and see” approach with respect to treatment, often choosing to treat just the symptoms with over-the-

counter medication in the early phases, rather than the disease itself. Compl. ¶¶ 33-34.¹ As the source explained, “[i]t’s only when patients begin to get more symptomatic, in what’s called more advanced intermediate stages, that drug treatment becomes employed.” *Id.* ¶ 35. Because many patients taking Jakafi during its launch were in the advanced stages of the disease, the drug’s heightened discontinuation rates for this group were the result of patient deaths or other serious side effects.

Discontinuation rates (and, conversely, persistency) were an important metric of the drug’s revenue. Plaintiff alleges Defendants were aware of the heightened discontinuation rates associated with Jakafi and knew the rates from the clinical trials were lower than the actual discontinuation rates in the field. Defendants thus misled the market during the Class Period by touting the clinical studies as a benchmark for patient usage instead of revealing the higher discontinuation rates, which would negatively affect the drug’s sales. Plaintiff alleges that by misrepresenting and concealing the true nature of Jakafi patient usage trends and results, Defendants artificially inflated Incyte’s stock price during the Class Period.

Plaintiff’s claims are based primarily on statements Defendants made during an April 26, 2012, conference call to discuss Incyte’s first-quarter 2012 financial results, and in a press release issued the same day. Plaintiff alleges as a result of these statements, and analysts’ response and commentary, Incyte’s stock jumped 18% between April 25 and April 27. Defendants allegedly made additional false and misleading statements during health conferences on May 15, June 6, June 7, June 19, and July 12, 2012. Between April 27 and August 1, 2012 (the last day of the Class Period), Incyte’s stock price climbed an additional 9%, which Plaintiff

¹ References and citations to the “Complaint” are to the Amended Consolidated Class Action Complaint filed on August 12, 2013.

alleges was due to the misleading statements made by Defendants at these health conferences. Plaintiff contends these statements, addressed specifically below, were false and misleading because they collectively suggested the discontinuation rates for Jakafi prescriptions during the Class Period were “consistent” with the rates recorded during the clinical trials, when Defendants knew the discontinuation rates in practice were in fact much higher than those associated with the clinical trials. *Id.* ¶ 48.

In the April 26, 2012, press release regarding Incyte’s first-quarter financial results, Incyte’s CEO Paul Friedman stated the “early response to Jakafi is encouraging” and the launch was “proceeding well.” *Id.* ¶ 45.² In the same press release, Friedman acknowledged physicians at the time were prescribing Jakafi “primarily for their more severely ill patients” but went on to note “we expect to see a gradual increase in the use of Jakafi among appropriate patients with less severe disease.” *Id.* ¶ 46; *see also* Defs.’ Mot. to Dismiss Ex. 5, at 1. During a conference call with analysts the same day, the Company’s COO, Patricia Andrews, made similar statements about the launch “going well,” noting, “[m]ost of our assumptions regarding initial patient use, physician mix, payer acceptance, and patient access are close to what we anticipated.” Compl. ¶¶ 47-48. She also discussed usage trends, acknowledging that the “usage [of Jakafi] is definitely at the moment in that more severe patient population. And we still have significant inroads to make there, as well as over the longer term in a patient population less burdened by the disease.” Defs.’ Mot. to Dismiss Ex. 8, at 7.

Andrews also participated in a question-and-answer session with analysts during the call. When asked about estimates for duration of therapy for patients on Jakafi, Andrews stated that

² Defendants made additional optimistic statements regarding the launch in the following months. *See* Compl. ¶ 59 (May 15, 2012, statement by Friedman noting “[w]e are encouraged by these first-quarter [Jakafi] sales, as well as the feedback from the field force.”); *id.* ¶ 62 (similar statements by Levy on June 7, 2012); *id.* ¶ 64 (similar statements by Levy on June 12, 2012).

since myelofibrosis is a chronic disease, and Jakafi is a chronic medicine, “many patients who go on [the] drug do, in fact, stay on it for many years.” Compl. ¶ 51. Another analyst asked Andrews about dose reduction related to Jakafi and she answered the question by noting it was too early to have any significant insight into that issue. *Id.* ¶ 52. When asked specifically about discontinuation rates and the general tolerability of the drug, Andrews responded

there’s really been nothing that we hadn’t anticipated, because we had done, really, an extensive amount of market research. So I think that it’s very much meeting our expectations in how we thought things would happen. Possibly initial uptake was a little bit faster than we thought, but that aside—and then, as far as early tolerability of the drug, which we know is very tolerable, but how is it in the real world, it would be too early for us to have significant insight into that. You know, the drug’s not been on the market that long, and most patients would have done one or two months of therapy at most. But we have a high level of confidence, based on the results from the clinical trials, that this is a well tolerated drug.

Id. ¶ 49. In response to a follow-up question as to whether there had been anything “anecdotal about patients dropping off the drug earlier than you would have expected,” Andrews stated, “No. No, there hasn’t been.” *Id.* ¶ 50.³

At a May 15, 2012, healthcare conference, Andrews repeated her earlier remarks that it was simply “too early to talk about discontinuations or adherence to therapy” but referred audience members to the 14% and 18% figures associated with the clinical trials. *Id.* ¶ 60. She then explained that discontinuations would likely be higher in the real world than in the clinical studies due to the severely ill patient population for whom the drug was being prescribed. *Id.* After addressing the reasons why discontinuation rates could potentially be higher in practice, Andrews noted that in the future she “would expect that discontinuations would decline and

³ Plaintiff also alleges the Company’s Form 10-Q, filed on April 26, 2012, contained material omissions because it did not disclose the true nature of the commercialization and patient usage results, trends, and prospects of Jakafi as alleged in the Complaint.

[ad]herence would increase just because the patient population becomes healthier.” *Id.*

On June 6, 2012, Andrews made similar comments regarding discontinuation rates, noting although it was too early to have a sense of discontinuation rates in the real world, “[w]e don’t have anything at the moment, which would lead me to think that [discontinuation rates] would be significantly different from what we saw in the [clinical] studies that I cited.” Compl. ¶ 61.⁴ After noting the possibility of a temporary increase in discontinuation rates due to the severely ill patient population being prescribed Jakafi, Andrews confirmed her belief that “[a]s we move into [a healthier] patient population, actually the reverse might occur and you might see less discontinuations.” *Id.*

During the June 7, 2012, conference, Friedman stated “[w]hat we expected to see when the drug was first approved was a higher proportion of patients who were too sick to get into the trial but were waiting for [the] drug. And we did see that; a lot of that is washed through. Product is growing nicely and steadily, just as Pat Andrews and her marketing team had predicted” *Id.* ¶ 62. Andrews and Levy expressed similar sentiments at the June 19, and July 12, 2012, conferences, that the phenomenon of more severely ill patients on Jakafi during launch was “to be expected.” *Id.* ¶ 63; *see also* Defs.’ Mot. to Dismiss Ex. 13, at 1-2. Nevertheless, Defendants were pleased with the success of the launch and the positive feedback from physicians regarding the drug, and predicted a steady increase in growth as more and more patients in the less advanced stages of the disease began taking Jakafi.

According to the Complaint, the “truth” regarding Jakafi’s discontinuation rates was

⁴ Andrews again acknowledged the possibility of a deviation from the results of the clinical studies, however, warning “there’s the wild card of what is it like in practice versus in a clinical study. Usually it’s slightly worse compliance or sometimes much worse compliance, and so that is still to play out.” Defs.’ Mot. to Dismiss Ex. 11, at 4.

revealed when Defendants issued Incyte's second quarter 2012 financial results on August 2, 2012. During a call with analysts, Andrews explained that some of the earliest patients were so ill that they would not have been eligible for the clinical trials. Compl. ¶ 67. She also stated it was still too early to discern any meaningful information regarding discontinuation rates, but acknowledged the discontinuation rates from the clinical trials reflected "the low end of the discontinuation rates we are likely to see commercially." *Id.* ¶ 67; *see also id.* ¶ 68 (statement by Friedman noting the discontinuation rates are "going to be probably slightly higher than the 14% to 18%, which is what you would expect out in the field as opposed to a controlled trial."). Defendants also disclosed that the time it would take to "evolve the use of Jakafi in the more severely ill patients . . . to the less severely ill" had an effect on the financial guidance Defendants issued regarding full-year 2012 Jakafi sales. Compl. ¶ 70; *accord* ¶ 53, Defs.' Mot. to Dismiss Ex. 6, at 1 (August 2, 2012, press release stating "[w]e continue to believe that growth will be steady as physicians gradually expand use to those appropriate patients who are less severely ill.").

While characterized by Plaintiff as revelations, in fact, many of these allegedly new truths were previously disclosed. For instance, with regard to certain patients being ineligible for the clinical trials, Friedman explained during the May 15, 2012, conference that many patients who had received Jakafi to that point had more severe symptoms and some of these patients were in such a late stage of the disease that they would have been precluded from participating in the clinical trial. He again acknowledged "[i]t will take time to expand the use of Jakafi in patients with less advanced disease." Defs.' Mot. to Dismiss Ex. 10, at 3; *see also* Compl. ¶ 62 (June 7, 2012, statement by Levy regarding Defendants' expectations that many initial patients were too sick to have participated in the trials), Defs.' Mot. to Dismiss Ex. 14, at 3-4 (July 12, 2012,

statements by Levy noting that patients with a baseline platelet count below 100,000 were not included in the original clinical trials).

Regarding the factors influencing Incyte's financial guidance as to full-year sales, Andrews stated on the April 26, 2012, earnings call that "[m]any of these physicians typically want more information, more education, and more time prior to prescribing a new product like Jakafi. . . . which is why we believe that, going forward, our growth rates for new prescribers and new patients may be more gradual than what we saw in the first quarter." Defs.' Mot. to Dismiss Ex. 8, at 4. At a health conference on June 6th, Andrews explained because earlier patients were more severely ill and the physicians were following the progress of the drug, she "view[ed] the remaining quarters of 2012 as having growth . . . of significance in a nice gradual pace. Probably not at the level of growth that we experienced in the first quarter because there was that front-loaded in acceleration" Defs.' Mot. to Dismiss Ex. 11, at 3.

As a result of Defendants' announcements on August 2, 2012, (and reports issued by analysts who considered heightened discontinuation rates to be a "key concern"), Incyte's stock dropped 27% in two days. *See* Compl. ¶¶ 71-72. After the Class Period, at another healthcare conference on November 15, 2012, Friedman stated the Company hoped to achieve a one-year discontinuation rate of 20% to 30% for relatively healthier patients with platelet counts above 100,000. The Company also acknowledged that following the launch, it did not have dosing information for how to manage the severely ill patients, i.e., those with platelet counts below 100,000.⁵ Andrews left the Company in August 2012, and in October 2012, Jim Daly replaced

⁵ Plaintiff alleges that one of the reasons Defendants' statements regarding discontinuation rates were false and misleading was because the lack of dosing information for patients with platelet counts below 100,000 on Jakafi's label during the launch contributed to higher discontinuation rates due to side effects associated with doctors prescribing Jakafi to those patients in inappropriately high dosages. *See* Compl. ¶ 58(c).

her as Incyte's Chief Commercial Officer. On August 1, 2013, approximately one year after the Class Period, Daly admitted that the discontinuation rates from the clinical trials were "unrealistic," stating those percentages were "probably an unrealistic hurdle, but having a 20% to 30% discontinuation rate at the end of 12 months we think that's achievable." *Id.* ¶ 80.

With respect to what Defendants knew regarding real-world discontinuation rates during the Class Period, and whether any documentation of those rates existed at the time, Plaintiff alleges that by virtue of their high ranking officer positions at Incyte, Defendants would have known the truth about Jakafi's higher discontinuation rates because they were privy to confidential proprietary information. Commercializing Jakafi was Incyte's core operation because Jakafi was its only commercial product, hence, Plaintiff infers Defendants would have carefully tracked and therefore would have had knowledge of Jakafi's patient useage, discontinuation rates, and patient deaths. Former employees (identified as confidential sources in the Complaint) noted the Company produced reports related to patient deaths on a monthly basis and tracked these deaths "pretty intently" as of December 2011/January 2012. *Id.* ¶ 39. The Company also allegedly tracked discontinuation rates and sales volume, prepared "discontinuation reports," and maintained data on intermediate-level risk patients and more severe patients. *Id.* ¶ 92.

On March 3, 2013, Plaintiff initiated this action by filing a complaint against Defendants. By Order of June 26, 2013, the Court consolidated this action with another pending action and appointed City of Lakeland Employees' Pension Plan as lead plaintiff for the class. Plaintiff then filed the Amended Consolidated Class Action Complaint on August 12, 2013. On September 26, 2013, Defendants filed the instant motion to dismiss, which Plaintiff opposes. Oral argument on the motion was held on December 19, 2013.

DISCUSSION

In deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), this Court must “determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a plausible claim for relief.” *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009). Courts must accept all of the plaintiff’s factual allegations as true and construe the complaint in the light most favorable to the plaintiff. *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008). To withstand dismissal, a complaint must contain “sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).⁶

Section 10(b) of the Securities Exchange Act makes it unlawful to “employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention” of any rule promulgated by the SEC designed to protect the investing public. 15 U.S.C. § 78j(b). Section 10(b) is enforced through SEC Rule 10b-5, which makes it unlawful: (1) “to employ any device, scheme, or artifice to defraud,” (2) “to make any

⁶ When evaluating a motion to dismiss a securities fraud action, “courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.” *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). In connection with their motion to dismiss, Defendants submitted a request for judicial notice of certain documents upon which Plaintiff bases its claims. These documents include various Incyte SEC filings, press releases, and transcripts of the conference calls during which the allegedly false statements were made. Plaintiff does not oppose Defendants’ request for judicial notice, and because Plaintiff’s Complaint refers to and quotes extensively from many of these documents, this Court finds it is appropriate to consider their contents in evaluating the instant motion to dismiss. See *Pension Benefit Guar. Corp. v. White Consolidated Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) (holding courts may consider “undisputedly authentic documents that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff’s claims are based on the document”).

untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading,” or (3) “to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person in connection with the purchase or sale of any security.” 17 C.F.R. § 240.10b-5. To state a claim for relief under Section 10(b) and Rule 10b-5, a plaintiff must plead facts demonstrating “(1) the defendant made a materially false or misleading statement or omitted a material fact necessary to make a statement not misleading; (2) the defendant acted with scienter; and (3) the plaintiff’s reliance on the defendant’s misstatement caused him or her injury.” *Cal. Pub. Emps.’ Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 143 (3d Cir. 2004).

Because this is a securities fraud action, Federal Rule of Civil Procedure 9(b) and the PSLRA provide additional considerations this Court must take into account when evaluating the sufficiency of the Complaint. Under Rule 9(b) a party “alleging fraud or mistake . . . must state with particularity the circumstances constituting fraud or mistake.” This heightened pleading requirement “has been rigorously applied in securities fraud actions,” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1417 (3d Cir. 1997), and requires plaintiffs to “support their allegations of securities fraud with all of the essential factual background that would accompany ‘the first paragraph of any newspaper story’—that is, the ‘who, what, when, where and how’ of the events at issue.” *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (citation omitted); *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 534 (3d Cir. 1999). A complaint which would normally survive a Rule 12(b)(6) motion may still fail on Rule 9(b) grounds. *In re Burlington*, 114 F.3d at 1424.

In an effort to restrict abuses in securities class action litigation, Congress passed the

PSLRA, which added even more stringent requirements to the heightened pleading standard of Rule 9(b). Where the plaintiff alleges the defendant made an untrue or misleading statement, the PSLRA “imposes two exacting and distinct pleading requirements.” *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 277 (3d Cir. 2010). To state a claim under the PSLRA, a plaintiff must (1) “specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading,” 15 U.S.C. § 78u-4(b)(1)(B), and (2) “state with particularity facts giving rise to a strong inference that the defendant acted with the requisite state of mind” *id.* § 78u-4(b)(2). A complaint alleging securities fraud under Section 10(b) and Rule 10b-5 must satisfy the heightened pleading requirements of both Rule 9(b) and the PSLRA. *Chubb*, 394 F.3d at 143-44.

Defendants primarily argue Plaintiff failed to establish the first element necessary to state a claim for a Section 10(b) violation—that Defendants made any materially false or misleading statements or omitted any material fact necessary to make a statement not misleading. While Plaintiff does identify with particularity the statements it believes are false and misleading,⁷ to state a claim under the PSLRA, Plaintiff must also state with particularity “the reason or reasons why the statement is misleading.” 15 U.S.C. § 78u-4(b)(1); *see also Institutional Investors Grp. v. Avaya*, 564 F.3d 242, 259 (“The first requirement under the PSLRA obliges a plaintiff to specify each allegedly misleading statement, the reason or reasons why the statement is misleading, and, if an allegation is made on information and belief, all facts supporting that belief with particularity.”). It is here that Plaintiff’s allegations fall short.

⁷ As discussed below, there is one exception to this finding. It is currently not clear whether Plaintiff contends Defendants’ predictions regarding growth in Jakafi sales and a future increase in prescriptions given to patients in the earlier stages of the disease are actionable. *See, e.g.*, Compl. ¶¶ 46, 53, 59-62, 64 (stating Defendants’ expectations in that regard).

In evaluating the sufficiency of Plaintiff's allegations as to how and why Defendants' statements are misleading, the Court must examine the various reasons provided by Plaintiff and the "true facts" alleged, which "are of paramount importance in this inquiry because they provide the exclusive basis for [Plaintiff's] claims that the various statements made throughout the Class Period were materially false and misleading." *Chubb*, 394 F.3d at 145. The gravamen of Plaintiff's action is that Defendants misled the market by representing that Jakafi's actual discontinuation rates during the Class Period were equal to the rates observed during the clinical trial. To satisfactorily allege that Defendants' statements were misleading under this theory, Plaintiff must plead particularized facts showing (1) Defendants actually represented that Jakafi's discontinuation rates in practice during the Class Period were consistent with discontinuation rates recorded during the clinical trials, and (2) concrete data existed during the Class Period indicating discontinuation rates in practice were in fact significantly higher than the clinical trial rates. Plaintiff cannot make either showing.⁸

First, Plaintiff has not pointed to any statements made by Defendants indicating the actual discontinuation rates for Jakafi during the Class Period were the same or consistent with the rates recorded during the clinical trials. While Defendants made certain statements suggesting the clinical trials could serve as a reference point to evaluate future discontinuation rates, any remarks to that effect came with significant caveats. Defendants never claimed to have any real world data about discontinuation rates in any of the statements on which Plaintiff relies. Indeed,

⁸ To state a claim for a Section 10(b) violation Plaintiff would also have to establish scienter, which requires alleging particular facts "giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2); *see also Tellabs*, 551 U.S. at 322-23. Establishing scienter under Plaintiff's theory of liability would require an additional showing that not only did data exist showing a significant divergence between the in-practice and clinical trial discontinuation rates, but also that Defendants knew about and had access to this data during the Class Period. For the reasons discussed below, the Court need not reach this inquiry.

a fair reading of the actual statements at issue shows the Defendants uniformly communicated to investors that it was too early to tell whether the discontinuation rates in practice would be consistent with the rates observed in the clinical trials. Defendants repeated this refrain throughout the Class Period. *See* Compl. ¶ 60 (May 15, 2012, statement by Andrews noting it was simply “too early to talk about discontinuations or adherence to therapy,” but referring audience members to the 14% and 18% figures associated with the clinical trials); *id.* ¶ 61 (June 6, 2012, statement by Andrews that “[i]t’s way too early to have a sense of discontinuation rate[s] or compliance in the real world, but we do look to our clinical trial data to inform what we believe is likely to happen”); *cf. id.* ¶ 52 (April 26, 2012, statement by Andrews noting it was too early in the launch to have much insight into dose reduction).

Plaintiff characterizes certain statements as misleadingly equating discontinuation rates recorded in practice with the clinical trial rates, but a close look at the statements permits no such inference. During the April 26, 2012, conference call, Andrews was asked about early patient dropouts and the general tolerability of the drug. She responded, “there’s really been nothing that we hadn’t anticipated. . . . But we have a high level of confidence, based on the results from the clinical trials, that this is a well tolerated drug.” *Id.* ¶ 49. Andrews’s reference to the clinical trials in this statement concerned the general tolerability of the drug among those who participated in the clinical trials. Potentially heightened discontinuation rates in the real world were, according to Plaintiff, largely a byproduct of the fact that physicians prescribed Jakafi mostly to patients in the advanced stages of the disease, including patients ineligible for the clinical trials—making the heightened rates attributable to patient deaths, not the general

tolerability of the drug.⁹ A statement during the Class Period suggesting Jakafi's tolerability was consistent with the findings in the clinical trials cannot be considered false or misleading absent allegations Jakafi was not generally well tolerated in practice. No such allegations exist.

Plaintiff also argues that during the same conference call, Andrews falsely stated "the patients that go on the drug, *the severely ill ones*, stay on for a very long time." Oral Arg. Tr. 50, Dec. 19, 2013, (emphasis added). The record does not support this characterization of her statement. During the call, Andrews was asked if she could talk about an estimate for duration of therapy for patients on Jakafi. She responded as follows:

So MF is a chronic disease, and Jakafi is a chronic medicine, so we would expect, just as we saw in the clinical trials, that many patients who go on [the] drug do, in fact, stay on it for many years. However, there will always be some patients who stay on it less and some who stay on it very long periods of time.

Defs.' Mot. to Dismiss Ex. 8, at 16. This statement cannot reasonably be understood to suggest that severely ill patients stay on Jakafi for long periods of time. Indeed, Andrews specifically acknowledged that some patients stay on Jakafi for many years, but others do not.¹⁰ Instead, her comment illustrates the unremarkable and truthful observation that Jakafi is a chronic medicine used to treat a chronic illness.

In a separate exchange on the conference call, Andrews was asked whether there was

⁹ Even if Andrews's comments in this regard did refer to discontinuation rates associated with the severely ill and patient deaths, the comments included a warning that discussion of in-practice rates would be premature. She stated "it would be too early for us to have significant insight into that. You know, the drug's not been on the market that long, and most patients would have done one or two months of therapy at most." Compl. ¶ 49.

¹⁰ Levy reinforced this qualification during the call. The questioner followed up on Andrews's remarks, asking if there was anything in the clinical trial data that suggested any duration of use. Levy answered by pointing out the results of the Phase II study showed "at that point, the median duration of treatment was about three years," but added, "as Pat said, clinical trials and real world can be somewhat different, and we just can't assess whether the real world is going to be matching that number yet. That's something we'll look at over the next couple of years." Defs.' Mot. to Dismiss Ex. 8, at 16.

anything anecdotal regarding patients dropping off the drug earlier than expected and she responded in the negative. Compl. ¶ 50. The analyst's question, however, did not seek a comparison with the clinical trials, but instead asked about Defendants' expectations, which were tempered by the acknowledged reality that doctors were, during the Class Period and the months following the launch, prescribing Jakafi disproportionately to the severely ill. *See id.* ¶¶ 62, 63 (stating Defendants' expectations regarding severely ill patients on Jakafi).¹¹ That doctors were prescribing Jakafi primarily to the severely ill during its launch was disclosed from the very beginning of the Class Period, in the press release associated with Incyte's first-quarter earnings announcement.

Operating from the unsupported premise that Defendants did in fact equate verifiable Class Period discontinuation rates with those from the clinical trials, Plaintiff next attempts to establish fraud by undermining the relevance of the clinical trial discontinuation rates to in-practice discontinuation rates. The Complaint does not specify any actual in-practice discontinuation rates, but according to Plaintiff, the reasons the clinical trials did not serve as an adequate reference point were threefold:

1. At Jakafi's launch, the core patient group for this drug was severely ill patients due to the slow-developing nature of myelofibrosis, which led physicians to employ a wait-and-see approach to its treatment, only using a drug like Jakafi when patients approached advanced intermediate stages.
2. The Company's touted clinical studies had little to no application to severely

¹¹ There is case law suggesting an anecdotal increase in patient dropouts during the Class Period need not be disclosed, particularly if any such increase was in line with Defendants' expectations. *See In re Viropharma, Inc. Sec. Litig.*, No. 02-1627, 2003 WL 1824914, at *6 (E.D. Pa. Apr. 7, 2003) ("Drug interaction data that is not statistically significant need not be disclosed in order to prevent prior statements about a drug's safety from becoming materially misleading." citing *Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000))). This point is significant when considering Plaintiff's failure to allege with particularity the existence of any concrete or statistically significant data generated by the Company that was in conflict with Defendants' statements.

ill patients who had not participated in those studies and thus were an “unrealistic” benchmark for patient usage and discontinuation rates among that patient population.

3. The dosage information that the Company had originally suggested was too high for the Company’s severely ill patient population with lower platelet counts, causing increased discontinuation rates (lack of persistency) among this core patient group.

Compl. ¶¶ 58, 66.¹² Yet far from being reasons why Defendants’ statements were misleading, these factors prompted Defendants to characterize their conclusions as tentative. Not only did Defendants qualify their statements by noting it was too early to draw any conclusions regarding discontinuation rates, they also described in detail the reasons why it could be possible that the in-practice rates might not be consistent with the clinical trial rates.

With regard to Plaintiff’s first reason, both the Complaint’s allegations and the documents incorporated by reference show Defendants repeatedly acknowledged the fact that severely ill patients were a significant subset of those being prescribed Jakafi during the Class Period. This information was not omitted or misrepresented. For instance, in the April 26, 2012, press release, Friedman acknowledged physicians at the time were prescribing Jakafi “primarily for their more severely ill patients.” *Id.* ¶ 46; *see also* Defs.’ Mot. to Dismiss Ex. 5, at 1. In the earnings call the same day, Andrews stated the “usage [of Jakafi] is definitely at the moment in

¹² Paragraph 58 of the Complaint lists the reasons why the April 26, 2012, statements were allegedly materially false and misleading; paragraph 66 refers to the reasons why the statements made at the health conferences were allegedly materially false and misleading. These reasons are substantively identical. Paragraph 58 contains two additional allegations regarding Incyte’s SEC filings. The first is that the Company’s first-quarter 2012 Form 10-Q was materially false and misleading because it failed to disclose materially adverse conditions to the market. The second is that the Sarbanes-Oxley Act certification executed by Friedman included a misleading representation that the Form 10-Q did not contain any untrue statements or material omissions when in reality, Defendants “knew but failed to disclose that the Company’s true drop-out rates were significantly higher than clinical studies and that the studies were not reflective of actual performance.” Compl. ¶ 58(g). These proffered reasons simply incorporate the other substantive allegations in the Complaint as the underlying basis for another misrepresentation or omission and therefore need not be considered independently.

that more severe patient population. And we still have significant inroads to make there, as well as over the longer term in a patient population less burdened by the disease.” Defs’ Mot. to Dismiss Ex. 8, at 7. Andrews even explained why doctors initially took a wait and see approach and prescribed Jakafi primarily to those at late stages of the disease, stating “[r]emember that [a] physician has the first belief of do no harm, they want to make sure that this is going to be the right drug for the right patient population hence we always expected that initial uptake would be in the more severely ill patient[s].” Defs.’ Mot. to Dismiss Ex. 10, at 4.

It is not clear from the face of the Complaint whether Plaintiff challenges Defendants’ expressed expectations that doctors would, in the future, increasingly prescribe Jakafi to less severely ill patients as the doctors became more comfortable with the drug. *See, e.g.*, Compl. ¶¶ 46, 53, 59-62, 64 (stating Defendants’ expectations in that regard). Assuming Plaintiff does contend these predictions were false or misleading, the Complaint is devoid of allegations showing how or why Defendants did not have a reasonable basis to believe that over time, discontinuation rates would decline as healthier patients were prescribed the drug in increasing numbers.¹³ Moreover, Defendants correctly predicted that Jakafi’s sales would gradually grow over time, and these predications were often pegged to an expectation that there would eventually be an increase in healthier patients taking Jakafi. *Compare* Defs.’ Mot. to Dismiss Exs. 5, 6, 91-95 (showing gradual growth in sales) *with* Compl. ¶¶ 46, 53, 59-62, 64, 70, and

¹³ The Complaint’s one allegation on this point is a statement from a former employee that “Incyte did not have a sound basis to project substantial sales from any patients who had less-than-severe symptoms.” Compl. ¶ 33. This allegation is wholly conclusory and insufficiently pleaded. It is nonspecific in time and there are no accompanying facts showing how this former employee was in a position to know whether this assertion was true either during or after Jakafi’s launch. *See Chubb*, 394 F.3d at 148 (describing requirements for allegations attributed to confidential sources). Additional pleading deficiencies with respect to Plaintiff’s confidential sources are discussed below.

Defs.’ Mot. to Dismiss Ex. 6, at 1 (August 2, 2012, press release stating “[w]e continue to believe that growth will be steady as physicians gradually expand use to those appropriate patients who are less severely ill.”).

Plaintiff’s second point regarding the exclusion of the severely ill from the original clinical trials is another fact Defendants repeatedly disclosed throughout the Class Period. *See* Defs.’ Mot. to Dismiss Ex. 10, at 3 (May 15, 2012, statement by Friedman explaining “most of the patients receiving Jakafi thus far . . . have more severe symptoms and larger spleen, in fact a subset of the patients . . . the severity of their disease would have precluded them from participating in the Phase III trial”); *id.* at 8 (statement by Andrews explaining “the discontinuations might be higher because the patients that were sicker or more severely ill . . . would go on the drug and they might not have been able to actually be eligible for the clinical trial and that would also be true with patients who had platelets less than 100,000”); Compl. ¶ 62 (June 7, 2012, statement by Friedman noting high proportion of patients “too sick to get into the trial”).

Plaintiff’s third reason Defendants’ statements were misleading involves allegations that the dosage information originally provided on Jakafi’s label was too high for the severely ill patients, causing heightened discontinuation rates. The product label at the time of the launch did not specifically suggest a starting dose for patients who began drug treatment with platelet counts lower than 100,000, even though the drug was approved for these patients. *See* Defs.’ Mot. to Dismiss Ex. 2 (June 2012 label).¹⁴ The label did recommend a specific starting dose for

¹⁴ Incyte’s April 26, 2012, press release did warn the public, however, that dose-related side effects could occur and “[p]atients with platelet counts less than $200 \times 10^9/L$ at the start of therapy are more likely to develop thrombocytopenia during treatment.” Defs.’ Mot. to Dismiss Ex. 5, at 5. The press release further advised “[t]hrombocytopenia was generally reversible and was usually managed by reducing the dose or temporarily withholding Jakafi.” *Id.*

patients with platelet counts higher than 200,000, and a reduced starting dose for patients with counts between 100,000 and 200,000. *Id.* Plaintiff alleges the lack of a starting dose recommendation for patients with platelets below 100,000 heightened the in-practice dropout rates because the severely ill patients “could not tolerate higher doses of the drug that were originally prescribed.” Compl. ¶ 76. This theory is flawed, however, because the Complaint contains no allegations allowing this Court to reasonably infer that any physicians did in fact prescribe Jakafi at inappropriately high doses to patients with platelet counts lower than 100,000.

Plaintiff has also failed to establish any connection between Jakafi’s label at launch and any potentially misleading statement made by Defendants. If it were not already clear from reading Jakafi’s label, which provided specific dosage recommendations for patients with platelet counts over 100,000, Levy stated on June 7, 2012, that Jakafi’s “current package insert does not give a starting dose recommendation for patients with platelet count less than 100,000.” Defs.’ Mot. to Dismiss Ex. 12, at 6. And as Plaintiff acknowledges in the Complaint, Jakafi’s drug label was eventually updated to include suggested dosages for more severely ill patients with lower platelet counts. *See* Compl. ¶ 5; *see also* Defs.’ Mot. to Dismiss Ex 2.2 (June 2013 label). The label update occurred after the Company conducted a further clinical trial involving severely ill patients with platelets lower than 100,000. Compl. ¶ 76. As a result of this additional trial, more information became available with regard to proper dosage for that subset of patients. *Id.* These facts are wholly consistent with Andrews’s remarks during the Class Period that it was “too early in the launch to have much insight into dose reduction.” *Id.* ¶ 52.

Although Defendants disclosed the underlying factors potentially influencing real-world discontinuation rates, Plaintiff argues Defendants failed to explain the implications of those factors. But Defendants did in fact connect the dots, acknowledging “discontinuations in the real

world might be higher than the clinical studies, attributable to the severely ill patient population,” Compl. ¶ 60; *see also id.* ¶ 61 (alleging Andrews acknowledged “discontinuation rates might ‘temporarily’ increase as a result of the severely ill patient population”). Contrary to Plaintiff’s suggestions, Defendants cautioned investors *not* to automatically assume the rates in the clinical trials would be illustrative of the rates in practice, because, as Andrews stated on May 15, 2012, “there’s the wild card of what is it like in practice versus in a clinical study. Usually it’s slightly worse compliance or sometimes much worse compliance, and so that’s still to play out.” Defs.’ Mot. to Dismiss Ex. 10, at 4. Plaintiff also maintains that by highlighting Defendants’ disclosures of the underlying factors that could cause actual discontinuation rates to diverge, Defendants are asserting a “truth on the market” defense, which is inappropriate on a motion to dismiss. Plaintiff is mistaken. Because a truth on the market defense presupposes the existence of misleading statements in the first place, there can only be a truth on the market defense if the allegations are first sufficient to establish a fraud on the market. For the reasons discussed at length in this Memorandum, Plaintiff has failed to make this showing.¹⁵

Plaintiff has also failed to allege with the requisite specificity that any data existed during the Class Period showing the Company was in fact experiencing heightened discontinuation rates at that time. Defendants’ Class Period statements, which collectively communicated that it was too early to tell whether discontinuation rates in practice would approach the rates seen in

¹⁵ Even if Defendants did need to resort to a truth on the market defense, such a defense can succeed on a motion to dismiss if “the company’s SEC Filings or other documents disclose the very information necessary to make their public statements not misleading.” *Wallace v. Sys. & Computer Tech. Corp.*, No. 95-6303, 1997 WL 602808, at *10 (E.D. Pa. Sept. 23, 1997) (citing *In re Stac Elec. Sec. Litig.*, 89 F.3d 1399, 1410 (9th Cir. 1996)). Here, the documents upon which Plaintiff relied in its Complaint show repeated disclosures of the information that would render Defendants’ statements not misleading. Thus, if a truth on the market defense were asserted and applicable on this motion to dismiss, its success is not necessarily foreclosed by the current procedural posture.

clinical trials, are only potentially misleading if—at the time the statements were made—there existed concrete data conclusively showing that discontinuation rates in practice were in fact much higher than the clinical trial rates. In this regard, Plaintiff contends Defendants’ statements were false and misleading because the “Defendants knew through, or recklessly disregarded, extensive market research, discontinuation reports, and constant monitoring that discontinuation rates were higher than expected due to patient death and serious side effects.” Compl. ¶ 58(d). This allegation, which concerns both the falsity of Defendants’ statements and Defendants’ knowledge of their falsity, prompts two separate inquiries. The first is whether Plaintiff sufficiently alleged that information inconsistent with Defendants’ statements existed during the Class Period; the second is whether Plaintiff sufficiently alleged Defendants acted with scienter. Because Plaintiff failed to satisfy the first inquiry, this Court need not reach the second.¹⁶

Put simply, Plaintiff has not alleged with the requisite particularity that there was

¹⁶ Because the Court finds the Complaint must be dismissed on the basis that Plaintiff has failed to sufficiently allege the existence of material misrepresentations or omissions, an analysis of whether the Complaint adequately pleaded facts giving rise to a strong inference of scienter is unnecessary. This Court notes, however, that many of the reasons why Plaintiff has failed to sufficiently allege the existence of any false or misleading statements are equally applicable to whether Defendants acted with scienter. Defendants’ statements during and after the Class Period both indicate it was too early during the Class Period to provide information on discontinuation rates experienced in the field. The consistency of their statements make it difficult for the Court to infer Defendants were in possession of any concrete data regarding in-practice discontinuation rates during the Class Period, let alone concrete data showing that in-practice rates were significantly higher than the rates recorded during the clinical trials. The mere facts that Defendants were involved in marketing research, Compl. ¶ 40, or were, as leading executives, generally in a position to know of heightened discontinuation rates are not, on their own, enough to establish scienter. *See In re Advanta*, 180 F.3d at 539 (“It is well established that a pleading of scienter may not rest on a bare inference that a defendant must have had knowledge of the facts.” (internal quotation marks omitted)). While this Court recognizes Plaintiff relies on other allegations regarding stock sales during the Class Period, taking the facts alleged as a whole, this Court cannot currently conclude on the basis of the Complaint that it was just as likely that Defendants acted with scienter as the inference they did not. *See Tellabs*, 551 U.S. at 323-24. Nor can this Court conclude that the existence of significantly heightened discontinuation rates in practice was a fact “so obvious that the actor must have been aware of it.” *Avaya*, 564 F.3d at 267 n.42.

anything to know regarding discontinuation rates during the Class Period that was inconsistent with Defendants' statements. In reaching this conclusion, the Court begins by considering Plaintiff's allegation that the Company generated contemporaneous "discontinuation reports" showing the actual discontinuation rates were "significantly different" than those recorded in the clinical trials. *See* Compl. ¶ 58(d), Pl.'s Opp'n at 9. Many of these allegations assert, in conclusory fashion, that discontinuation reports existed, but none provide sufficient detail to meet the pleadings standards imposed by Rule 9(b) and the PSLRA. Where, as here, allegations are made on information and belief, "the complaint must not only state the allegations with factual particularity, but must also describe the sources of information with particularity, providing the who, what, when, where and how of the sources, as well as the who, what, when, where and how of the information those sources convey." *Avaya*, 564 F.3d at 253. More specifically, where allegations are based on alleged internal reports, the Third Circuit has instructed a plaintiff must, for example, "specify the internal reports, who prepared them and when, how firm the numbers were or which company officers reviewed them." *Chubb*, 394 F.3d 147 (quoting *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 72 (2d Cir. 2001)).

Plaintiff has provided none of the particularized facts required by *Chubb*, nor have they described the who, what, when, where, and how of the information associated with or contained within the alleged discontinuation reports. Plaintiff does not state who authored the reports; who specifically reviewed the reports (aside from the conclusory assertion they were made available to Defendants); what data informed the reports or what these reports allegedly revealed regarding the "true" nature of the discontinuation rates in practice, apart from alleging the reports showed discontinuation rates were "higher" during the Class Period than the rates from the clinical trials.

See Compl. ¶ 7.¹⁷ Because Plaintiff has failed to provide particularized facts regarding the generation of any reports and the information allegedly contained in them, the Court cannot infer the reports exist and contain information inconsistent with Defendants’ statements. *See Chubb*, 394 F.3d at 145 (“[U]nless plaintiffs in securities fraud actions allege facts supporting their contentions of fraud with the requisite particularity mandated by Rule 9(b) and [the PSLRA], they may not benefit from inferences flowing from vague or unspecified allegations—inferences that may arguably have been justified under a traditional Rule 12(b)(6) analysis.”) (quoting *In re Rockefeller*, 311 F.3d at 224). In the absence of such an inference, Plaintiff cannot establish Defendants made any false or misleading statements or omitted any material information, and the Complaint must be dismissed.

In addition to alleging the existence of contemporaneous “discontinuation reports,” Plaintiff also relies on certain confidential sources to establish that information existed during the Class Period showing discontinuation rates in practice were in fact much higher than rates associated with the trials. “Where, as here, plaintiffs lack documentary evidence such as internal memoranda, reliance on confidential sources to supply the requisite particularity for their fraud claims . . . assumes a heightened importance.” *Avaya*, 564 F.3d at 261 (citations and internal quotation marks omitted). In general, a confidential source’s allegations must be described with “sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged.” *Chubb*, 394 F.3d at 148 (quoting *Novak v. Kasaks*, 216 F.3d 300, 313-14 (2d Cir. 2000)). Thus, when considering confidential sources’

¹⁷ When asked if reports actually exist showing that the dropout rates were higher in practice, Plaintiff responded “[i]f they do, I don’t know it.” Oral Arg. Tr. 55. Plaintiff contends, however, that it does not need to allege this information because Defendants’ statements after the Class Period confirm that the reports existed and showed the rates were in fact higher. Plaintiff’s allegations in this regard are addressed below.

statements, a court must examine the “detail provided by the confidential sources, the sources’ basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia.” *Avaya*, 564 F.3d at 261 (quoting *Chubb*, 394 F.3d at 147).

The Court need not consider at length the sufficiency of Plaintiff’s allegations based on confidential sources, because Plaintiff conceded at oral argument that the sources “did not know or were not in a position to know that the rates were higher in the actual group that was getting the medicine versus the clinical trials.” Oral Arg. Tr. 44.¹⁸ Because establishing a known and verifiable discrepancy that existed during the Class Period between real-world and clinical trial discontinuation rates is the only method by which this Court might plausibly infer Defendants’ statements were misleading, Plaintiff’s reliance on these confidential sources is unavailing.¹⁹ Plaintiff alleges one confidential source had knowledge of higher discontinuation rates based on a conversation he or she had with Levy. *See* Compl. ¶ 39. Levy allegedly informed the source “the reason for the unexpectedly high death rate was that more seriously ill patients were being treated in practice than in clinical trials, and these more severe patients were prone to dying,

¹⁸ Plaintiff went on to note “by [and large] the four or five cooperating witnesses that are relied on in this case are for background.” *Id.* This Court may consider statements made by counsel at oral argument to clarify allegations made in the Complaint. *See Maio v. Aetna, Inc.*, 221 F.3d 472, 485 n.12 (3d Cir. 2000).

¹⁹ Aside from the existence or non-existence of the so-called “discontinuation reports,” Plaintiff also alleges the Company “began tracking actual patient deaths ‘pretty intently’ as of December 2011/January 2012.” Compl. ¶ 39. This allegation is also insufficient. It is not clear from the Complaint how or if the confidential witness providing this information was in a position to know it, and it is also not clear what was meant by “tracking,” what information that tracking produced, and how this tracking sheds meaningful light on the discontinuation rates experienced in the field. *Cf. Chubb*, 394 F.3d at 152 (finding allegations deficient where Complaint failed to “identify the data, or source of data, used to arrive at its calculations” and where plaintiffs did not “provide any particulars regarding the amount by which reserves were distorted, or how much revenue was improperly recognized”).

given their advanced stages.” *Id.*²⁰ This information is entirely consistent, however, with what Defendants already disclosed throughout the Class Period. For these reasons, Plaintiff’s allegations involving confidential sources are currently deficient both in substance and form. *See Avaya*, 564 F.3d at 280 n.33.

Plaintiff also maintains Defendants’ post-Class Period statements demonstrate the falsity of their earlier statements. Here, as in *Chubb*, however, “Defendants’ supposed ‘admissions’ . . . are, in fact, generally consistent with what Plaintiff[] deem[s] were Defendants’ false statements and disclosures.” *Chubb*, 394 F.3d at 156. At the second quarter earnings conference call on August 2, 2012, Defendants still maintained it was too early to determine what the discontinuation rates would be in the field. Andrews stated the clinical trials reflected “the low end of the discontinuation rates we are *likely* to see commercially.” Compl. ¶ 67 (emphasis added). Use of the word “likely” implies it was still too early to have concrete data regarding Jakafi’s real-world rates. Other statements included similar qualifiers. *See, e.g.*, Compl. ¶ 68 (August 2, 2012, statement by Andrews that “we would *expect* [clinical discontinuation rates] to be probably the low end of what we see commercially” (emphasis added)). Friedman continued, “what Pat [Andrews] has said is that you would expect, when we do finally asymptote to a more

²⁰ This statement from the Complaint is not a quote from a confidential source, and it is not clear whether the phrase “unexpectedly high death rate” is attributable to the source. The source stated directly “[i]t was pretty clear, perhaps there were more deaths than management might have expected.” Compl. ¶ 39. This statement is vague, equivocal, and entirely conclusory. Leaving aside the issues regarding how the source knew of Defendants’ expectations, the Complaint does not indicate whether Defendants actually had any specific expectation regarding discontinuation rates for severely ill patients or overall discontinuation rates during the Class Period, or if they did, what those expectations were. Other allegations in the Complaint and disclosures made by Defendants suggest that a higher death rate due to the severely ill patient population was in fact expected by Defendants. *See e.g., id.* ¶ 63 (alleging Andrews stated “the phenomenon of more severely ill patients on Jakafi was ‘to be expected.’”); Defs.’ Mot. to Dismiss Ex. 8, at 4 (April 26, 2012, statement by Andrews noting “[o]ur market research suggests that most patients receiving Jakafi thus far tend to have severe symptoms and larger spleens. This is consistent with our original expectations.”).

or less steady-state discontinuation rate, it is going to be probably slightly higher than the 14% to 18%, which is what you would expect out in the field as opposed to a controlled trial.” *Id.* Not only are these statements consistent with the message that it was too early during the Class Period to have any meaningful information on discontinuation rates in the field, they are also consistent with Defendants’ cautions that the rates may in fact vary.

Defendants also acknowledged on August 2, 2012, that the presence of the severely ill as a subset of patients prescribed Jakafi in practice had an effect on the financial guidance, but Defendants had previously disclosed this potential effect on the very first day of the Class Period.²¹ The projected revenues and sales guidance issued on August 2, 2012, prompted negative feedback from analysts, causing Incyte’s stock price to fall. *See* Compl. ¶ 71. Defendants had not previously issued any guidance with respect to sales, but their earlier predictions were consistent the August 2, 2012, guidance implying “modest [quarter-over-quarter] growth.” *Id.* Nevertheless, Incyte’s conservative guidance was apparently inconsistent with and “disappointed high [Wall] Street expectations.” *Id.* Although Plaintiff maintains its allegations are not contingent upon whether Defendants made accurate predictions of revenue, it bears noting that Defendants’ predictions of gradual growth, which they maintained throughout

²¹ *See, e.g.*, Defs.’ Mot. to Dismiss Ex. 8, at 4 (April 26, 2012, statement by Andrews noting “[m]any of these physicians typically want more information, more education, and more time prior to prescribing a new product like Jakafi. . . . which is why we believe that, going forward, our growth rates for new prescribers and new patients may be more gradual than what we saw in the first quarter.”); *see also* Defs.’ Mot. to Dismiss Ex. 11, at 3 (June 6, 2012, statement by Andrews noting that early on Jakafi’s sales were frontloaded with prescriptions for the severely ill, but viewing “the remaining quarters of 2012 as having growth . . . of significance in a nice gradual pace. Probably not at the level of growth that we experienced in the first quarter because there was that front-loaded in acceleration, but nice sustainable growth over the rest of this year and for next year”).

the Class Period, turned out to be correct. *See* Defs.’ Mot. to Dismiss Exs. 5, 6, 91-95.²²

This Court cannot reasonably infer that any of the statements identified in paragraphs 73-80 of the Complaint show conclusive and statistically significant data existed during the Class Period indicating that discontinuation rates were much higher in practice than in the clinical trials. Even the statement made by Daly in August 2013, one full year after the end of the Class Period, acknowledges only that the clinical rates are “*probably* an unrealistic hurdle, but having a 20% to 30% discontinuation rate at the end of 12 months we think that’s achievable.” Compl. ¶ 80 (emphasis added). The fact the language used by Company representatives one year later remains tentative further suggests the Company was not, during the Class Period, in possession of concrete information regarding the discontinuation rates experienced in practice.

Moreover, that real world discontinuation rates may have turned out to be higher than those from the clinical studies is irrelevant because the Third Circuit has “long rejected attempts to plead fraud by hindsight.” *Chubb*, 394 F.3d at 158; *id.* (“We have been clear that fraud cannot be inferred merely because ‘[a]t one time the firm bathes itself in a favorable light’ but later the firm discloses that things are less than rosy.” (quoting *In re Advanta*, 180 F.3d at 538)); *see also In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir.2002) (“To be actionable, a statement or omission must have been misleading at the time it was made; liability cannot be imposed on the basis of subsequent events.”).

Defendants’ remaining allegedly false and misleading statements—in which Defendants described the launch as “going well” and described the early response to Jakafi as

²² Plaintiff also asserts, as another reason why Defendants’ statements were allegedly false and misleading, that “the increase in discontinuations at the same time that new patient additions were only increasing minimally led to a slowdown in net patient additions.” Compl. ¶ 58(e). To the extent Plaintiff is referring to a slowdown between first quarter sales compared to subsequent quarters, again, the guidance issued by Defendants on August 2, 2012, was consistent with their disclosures and their growth predictions from the outset—steady, gradual growth. *See id.* ¶ 53.

“encouraging”—are not actionable. *See* Compl. ¶¶ 45, 47-48, 59, 62, 64. General statements of optimism such as these have been uniformly held to be immaterial and “too vague to be actionable.” *See In re Burlington*, 114 F.3d at 1428 (holding the company’s statement it believed it could “continue to grow net earnings at a faster rate than sales” was too vague to be relied upon by a reasonable investor); *see also Aetna*, 617 F.3d at 284 (upholding the district court’s finding that the defendants’ statements regarding “disciplined” pricing were “immaterial and not actionable because they [were] puffery, vague and non-specific expressions of corporate optimism on which reasonable investors would not have relied”).

For the reasons set forth above, Plaintiff has failed to adequately state a claim for a violation of Section 10(b) of the Securities and Exchange Act. Since Plaintiff failed to state a valid claim under Section 10(b), the Section 20(a) claims must also be dismissed. *See In re Advanta*, 180 F.3d at 541. Dismissal of Plaintiff’s claims will be without prejudice, and the Court will grant Plaintiff’s request for leave to amend the Complaint to address the failure to plead fraud with sufficient particularity, which now requires dismissal under Rule 9(b) and the PSLRA.²³

²³ Certain concessions made by Plaintiff during oral argument suggest amendment may be futile, as its confidential sources may not be able to establish with the requisite particularity the allegations that data documenting and reports analyzing discontinuation rates existed during the Class Period. If it is indeed true that Plaintiff can rely only on Defendants’ post-Class Period statements to demonstrate the falsity of Defendants’ assertions that it was premature during the Class Period to discuss in-practice discontinuation rates, Plaintiff may continue to be unable to state a claim. This Court cannot at this time, however, conclude with certainty that amendment would be futile. Because the Court is “hesitant to preclude the prosecution of a possibly meritorious claim because of defects in the pleadings,” Plaintiff shall “be afforded an additional, albeit final opportunity, to conform the pleadings to Rule 9(b).” *In re Burlington*, 114 F.3d at 1435 (quoting *Ross v. A.H. Robins Co.*, 607 F.2d 545, 547 (2d Cir. 1979)). Having concluded that Plaintiff failed to adequately allege the existence of any false or materially misleading statements, the Court need not parse each statement to determine whether the safe harbor provision of the PSLRA applies. *See* 15 U.S.C. § 78u-5(c) (creating a statutory allowance for forward-looking written or oral statements). If Plaintiff is able to amend its Complaint to include

An appropriate Order follows.

BY THE COURT:

/s/ Juan R. Sánchez
Juan R. Sánchez, J.

the specificity necessary to state a claim under Rule 9(b) and the PSLRA, this Court will analyze at that time whether the safe harbor and the bespeaks caution doctrine apply to immunize Defendants' statements from liability.